



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gallet et al.

U.S. Appln. Serial No.: 09/937,045

Filing Date: 20 September 2001

Group Art Unit: 1624

Examiner: Brenda Libby Coleman

For: **DERIVATIVES OF 1,4-DIAZABICYCLO[3.2.2]NONANE-4-CARBOXYLATES AND -CARBOXAMIDES, THEIR PREPARATION AND THEIR THERAPEUTIC APPLICATION**

**CERTIFICATE UNDER 37 C.F.R. 1.8(a)**

I hereby certify that this correspondence is being deposited on the date indicated below with the United States Postal Service as first class mail addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Name

Date

October 20, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**RESPONSE**

This is in response to the Office Action mailed on June 3, 2004, by the United States Patent and Trademark Office setting a three-month period for response which was set to expire on September 3, 2003. The three-month shortened statutory period for response is hereby extended by two months to November 3, 2004, pursuant to the Petition for Extension of Time under 37 C.F.R. §1.136(a), which is submitted herewith.

Claims 1-3 were in the application as originally filed. Claim 2 was canceled and claims 4-6 were added in the Preliminary Amendment filed on September 20, 2001. Claims 7-10 were added in the amendment filed on March 1, 2004. Claims 1 and 3-10 remain in the application.

The rejection of claims 1, 3, and 5 under 35 U.S.C. §112, first paragraph, for containing subject matter which was not described in the specification, has been maintained. In support of this rejection, the Examiner has stated that:

The applicants' stated that claim 1, as amended, provides that the group "nitro" is a possible alternative for only the R<sub>3</sub> substituent. The applicants' also stated that the specification clearly sets forth that "nitro" is a possible R<sub>3</sub> substituent (see table on page 9 of the specification), surely it cannot be said that Applicants were not in possession of the claimed invention at the time the instant application was filed. However, the definition of X, n, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, and R<sub>5</sub> on page 9 is part of a table of specific species, with specific definitions for each of the variables, not the description of the genus of Formula 1. Additionally, recent case law *Tronzo v. Biomet* 47 USPQ2d 1829 states that a species in a prior application does not provide written description to a generic claim.

This rejection is traversed and reconsideration and withdrawal thereof are requested for the reasons given hereinbelow.

The Examiner relies on the opinion of *Tronzo v. Biomet* for the proposition that a species in a prior application does not provide written description to a generic claim. Applicants respectfully submit that the fact situation in *Tronzo* differs significantly from the fact situation at bar. In *Tronzo*, the disclosure of only one or two species in the parent application was insufficient to provide adequate written description or inherent disclosure of a broad genus claimed in the child application. Accordingly, the parent application failed to describe an adequate number of species that, in aggregate, could demonstrate that the inventor was in possession of the genus claimed in the child application. The *Tronzo* case, however, does not stand for the proposition that the written description requirement for a claimed genus can no longer be satisfied unless the genus itself is explicitly, as opposed to inherently or implicitly, set forth in the application as filed. Claiming a genus based on an aggregate of disclosed species is still consistent with PTO practice, as stated in MPEP 2163.05:

***Addition of a Generic Claim***

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus.

Applicants previously amended claim 1 to provide a “nitro” group as a possible alternative for the R<sub>3</sub> substituent. The specification clearly describes a “nitro” group as a possible R<sub>3</sub> substituent (see table on page 9 of specification). Thus, claim 1, as amended, is merely a generic claim based on a previously disclosed genus of compounds and a previously described species, and such combination is fully supported by a representative number of species set forth in the specification. Hence, Applicants have satisfied the written description requirement and were clearly in possession of the claimed invention at the time the instant application was filed. Accordingly, no basis is seen for the rejection of claims 1, 3, and 5 under U.S.C. §112, first paragraph, and the rejection should, therefore, be withdrawn

Claims 4 and 6 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. With respect to Applicants’ previous response, the Examiner states the following:

The applicants’ stated that the 23 examples set forth in the table on page 9 of the specification in aggregate amount to the subgenus described in instant claim 4. However, the definition of X, n, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub> and R<sub>5</sub> as set forth in the table on page 9 is a table of specific species, with specific definitions for each variables, not the description of subgenus of Formula I. Additionally, recent case law *Tronzo v. Biomet* 47 USPQ2d 1829 states that a species in a prior application does not provide written description to a generic claim.

This rejection is traversed and reconsideration and withdrawal thereof are requested for the reasons given hereinbelow.

As stated hereinabove, the fact situation in *Tronzo* differs significantly from the fact situation at bar and does not support the instant rejection. The *Tronzo* court held that the species in the parent application did not provide adequate written description to a generic claim in the child application. However, the rejected claim in the cited case contained a broad genus for which only one or two species were described in the parent case. On the other hand, Applicants, in the instant case, have written a sub-generic claim based on an aggregate of 23 examples or “species” set forth in the table on page 9 of the specification. As previously pointed out by Applicants, the description requirements of 35 U.S.C. § 112, paragraph one, may be satisfied by

either a description in the specification as filed of the subgenus *or* a description of species thereof amounting, in aggregate, to the same thing, which is on point with MPEP 2163.05:

***Addition of a Generic Claim***

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus.

The description of the 23 examples in the table amounts in aggregate to the subgenus of claims 4 and 6, and such species are representative of the entire subgenus herein claimed, and thus, satisfy the written description requirement under 35 U.S.C. § 112, first paragraph. Therefore, the rejection of claims 4 and 6 under 35 U.S.C. §112, first paragraph, is unwarranted and withdrawal thereof is respectfully requested.

Claims 7-9 are deemed to be allowable but are objected to as being dependent on rejected base claims. In view of the foregoing arguments, claims 1, and 3-6 are believed to be allowable, and, accordingly, claims 7-9 should be allowable in dependent form.

In view of the foregoing remarks, reconsideration and withdrawal of the rejection of: a) claims 1, 3, and 5 under 35 U.S.C. §112, first paragraph, and b) claims 4 and 6 under 35 U.S.C. §112, first paragraph, and allowance of claims 1 and 3-10 is respectfully requested.

Respectfully submitted,

Dated: October 20, 2004



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